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EXAMINER

SCHWARTZ, JORDAN MARC

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2873

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/910,355

Applicant(s)

MARMO, J. CHRISTOPHER

Examiner

Jordan M. Schwartz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claims 1-40, all of the claims use the term "microchannels" which is defined in the specification in conflicting and varying manners which renders the claims vague and indefinite. On page 12, line 12, "microchannel" is defined as "a fine groove preferably less than 100 microns in depth or width" and the "preferably" language creates the indefiniteness since it is not clear as to what depth or width is required in order to be considered a "microchannel". Furthermore, page 6, line 20 and page 12, line 30 describe widths as large as 500 microns, which conflicts with this definition. Furthermore, page 6, line 21 says the depth can be up to 90% of the thickness and the specification says that the lens can have a thickness of 120 microns and 90% would be 108 microns, again conflicting with the aforementioned definition. Furthermore, page 6, line 9 defines "microchannel" as 'having a width of less than about 10 degrees, preferably less than about 5 degrees, and more preferably in a range of about 0.5 to about 2 degrees" and the "preferably" language as well as the varying and conflicting definitions of "microchannel" renders the claims vague and indefinite.

In reference to claims 1 and 25 (and respective dependent claims 2-18 and 26-31), the claims state "without substantially interfering with optical zone function" which limitation renders the claims vague and indefinite. Specifically, it is not clear as to the

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amount of optical zone interference that is permitted in order to not be considered "substantially interfering" and the lack of clarity renders the claims vague and indefinite.

In reference to claim 24, "the optical zone" lacks an antecedent basis creating the lack of clarity. Specifically, claim 24 depends from claim 19, which has not claimed that the lens provides any optical correction or has an "optical zone". If "optical zone" is intended as a limitation then it needs to be more positively and distinctly claimed.

In reference to claim 32, the claim uses the term "substantially continuous freely flowing tear film" which is defined in the specification in a way that creates a lack of clarity. Specifically, page 7 defines this term with "at least about 50% or at least about 70% or at least about 80%..." and it is not clear as to what percentage is required to be considered "substantially continuous freely flowing tear film".

### ***Claim Objections***

Claims 3 and 20 are objected to because of the following informalities:

1. in reference to claim 3, the claim needs to end in a period.
2. in reference to claim 20, the word 'herein' should be corrected to "wherein".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-14, 17 and 25-40 are rejected under 35 U.S.C. 102(b) as being anticipated by DE-2546692 (hereinafter referred to as "DE'692").

DE'692 reads on these claims by disclosing the limitations therein including the following: a contact lens for use on an eye (English abstract) comprising a plurality of radially extending microchannels in the posterior face (English abstract, Figure 5); to promote the effective tear fluid exchange between the exposed surface of the eye and a surface covered by the lens body (English abstract). DE'692 further discloses the microchannels sized and adapted to not interfere with the optic zone function in that the channels are disclosed as not extending into the optic zone (Figure 5). DE'692 further discloses an absence of microchannels in the optic zone (Figure 5); the microchannels having a decreased taper in terms of width (Figure 5); the microchannels equidistantly spaced apart (Figure 5). In reference to claim 17, in Figure 5, any several of the microchannels can be considered as the "first set" and any other several microchannels can be considered as the "second set" and inherently some of the lachrymal fluid that flows into the lens through channels of the first set will flow out of the lens through channels of the second set (the fluid does not flow in and out through the same channel) and therefore the sets can be considered "in fluid communication with each other". It is believed that DE'692 would inherently have the amount of microchannels within the claimed ranges, spaced apart within the claimed ranges, and the claimed width and depth within the claimed ranges, as well as the microchannels providing substantially continuous, freely flowing tear film (to the extent this is understood), this being reasonably based upon the very large ranges claimed as well as upon the

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similarity in structure between DE'692 and that of the claimed invention.

Claims 1-14, 17 and 25-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Haralambopoulos et al patent no. 5,598,233.

Haralambopoulos et al reads on these claims by disclosing the limitations therein including the following: a contact lens for use on an eye (abstract) comprising a plurality of radially extending microchannels in the posterior face (Figures 3A-3B, 5 and 7, column 3, lines 6-22); to promote the effective tear fluid exchange between the exposed surface of the eye and a surface covered by the lens body (column 3, line 6 to column 6, line 3); the microchannels sized and adapted to not interfere with the optic zone function (Figures 3A-3B, column 3, lines 6-22). Haralambopoulos et al further discloses an absence of microchannels in the optic zone (Figures 5 and 7); the microchannels having a decreased taper in terms of width or depth (column 7, line 5); the microchannels equidistantly spaced apart (Figures 5, 7 and 8); comprise the number of microchannels within the claimed ranges (column 5, line 58). In reference to claim 17, in Figure 5, any two of the microchannels can be considered as the "first set" and the other two microchannels can be considered as the "second set" and inherently some of the lachrymal fluid that flows into the lens through channels of the first set will flow out of the lens through channels of the second set (the fluid does not flow in and out through the same channel) and therefore the sets can be considered "in fluid communication with each other". It is believed that Haralambopoulos et al would inherently have the microchannels spaced apart within the claimed ranges, this being reasonably based upon Haralambopoulos et al disclosing the microchannels as evenly spaced apart

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(column 5, line 40 and that Haralambopoulos et al can comprise numerous channels re column 5, line 58 and having between 12 and 72 channels would inherently provide the claimed spacing of the channels). Haralambopoulos et al would inherently have the claimed width and depth within the claimed ranges, as well as the microchannels providing substantially continuous, freely flowing tear film (to the extent this is understood), this being reasonably based upon the very large ranges claimed, that the channels can be "slits" (column 6, lines 11-21) and the similarity in structure between Haralambopoulos et al and that of the claimed invention.

Claims 19-22, 32-35 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Ridell patent no. 2,393,266.

Ridell reads on these claims by disclosing the limitations therein including the following: a contact lens for use on an eye (column 1, line 1); a first set of microchannels within a first annular portion of the posterior face (Figure 1, the innermost radially extending channels); a second set of microchannels within the second annular portion of the posterior face (Figure 1, the outermost radially extending channels); the first and second set in optical communication with each other (Figure 1); the claimed annular microchannel between the first and second set (Figure 1, the annular microchannels); the claimed number and spacing of the microchannels (Figure 1). In reference to claim 22, four of the inner channels can be considered as the "first set" (for example) and eight of the outer channels can be considered as the "second set" (for example) and therefore the first set would have relatively fewer microchannels than the second set. It is believed that Ridell would inherently have the claimed width and depth

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within the claimed ranges, as well as the microchannels providing substantially continuous, freely flowing tear film (to the extent this is understood), this being reasonably based upon the very large ranges claimed.

Claims 1-5, 7-14, 17-18, 25-27, 29-37 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Volk patent no. 5,347,326.

Volk reads on these claims by disclosing the limitations therein including the following: a contact lens for use on an eye (abstract) comprising a plurality of radially extending microchannels in the posterior face (Figure 12, column 14, lines 3-29); to promote the effective tear fluid exchange between the exposed surface of the eye and a surface covered by the lens body (column 14, lines 3-29 and claim 12 in which it is stated that the channels both remove air and allow the flow of tear fluid). Volk further discloses the microchannels sized and adapted to not interfere with the optic zone function in that the channels are disclosed as not extending into the optic zone (Figure 12). Volk further discloses an absence of microchannels in the optic zone (Figure 12); the microchannels having a decreased taper in terms of width (Figure 12 i.e. there is some width taper near the ends of the channels); the microchannels equidistantly spaced apart (Figure 12). In reference to claim 17, in Figure 12, any two of the microchannels can be considered as the "first set" and any two microchannels can be considered as the "second set" and inherently some of the lachrymal fluid that flows into the lens through channels of the first set will flow out of the lens through channels of the second set (the fluid does not flow in and out through the same channel) and therefore the sets can be considered "in fluid communication with each other". In reference to



claim 18, Volk further discloses the annular microchannel between (Figure 12, "106"). It is believed that Volk would inherently have the amount of microchannels within the claimed ranges, spaced apart within the claimed ranges, the claimed width and depth within the claimed ranges, as well as the microchannels providing substantially continuous, freely flowing tear film (to the extent this is understood), this being reasonably based upon the vary large ranges claimed as well as upon the similarity in structure between Volk and that of the claimed invention.

***Prior Art Citations***

Conrad et al patent no. 3,431,046, Moss patent no. 3,246,941 and Porat (Figures and column 4, lines 14-18) are being cited herein to show contact lenses that would read on a number of the above rejected claims, however, such rejection would have been repetitive.

***Allowable Subject Matter***

Claims 15-16 and 23-24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: with respect to the allowable subject matter, none of the prior art either alone or in combination disclose or teach of the claimed combination of limitations to warrant a rejection under 35 USC 102 or 103. Specifically, with respect to claims 15-16, none of the prior art either alone or in combination disclose or teach of the contact lens comprising an optical portion, a plurality of radially extending microchannels sized and

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adapted to promote effective tear fluid exchange between an exposed surface of the eye and a surface of the eye covered by the lens body without substantially interfering with the optical zone function (as this is understood) and specifically further including first microchannels only in the peripheral portion and second microchannels at least partially in the optic zone. Specifically, with respect to claim 23, none of the prior art either alone or in combination disclose or teach of the contact lens comprising a first annular portion, a second annular portion circumscribing the first annular portion, first set of microchannels in the first portion, a second set of microchannels in the second portion, the first and second portion in optical communication with each other and specifically further with the lens body including an optical zone and the first set of microchannels extending from an edge of the optical zone to the peripheral edge. Specifically, with respect to claim 24, none of the prior art either alone or in combination disclose or teach of the contact lens comprising a first annular portion, a second annular portion circumscribing the first annular portion, first set of microchannels in the first portion, a second set of microchannels in the second portion, the first and second portion in optical communication with each other and specifically further an absence of microchannels in the optical zone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (703) 308-1286. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (703) 308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

A handwritten signature in black ink, appearing to read 'J. Schwartz', with a stylized, cursive script.

Jordan M. Schwartz  
Primary Examiner  
Art Unit 2873  
February 6, 2003